REMARKS

FORMAL MATTERS:

Claims 29 and 41-56 are pending and stand rejected.

Claims 29, 42, 44-46, 49-51, 53-55 are amended for clarity. Support for the amendments can be found on page 12, line 25, in the table bridging pages 24 and 25, the paragraph starting on line 7 of page 49, Fig. 2. Support for the amendment to the specification is found in lines 9 to 23 of page 28 of provisional application serial no. 60/282,356, which application is incorporated by reference in the first paragraph of the instant application.

Claims 41, 43 and 57-61 are cancelled without prejudice to renewal.

No new matter is added.

In view of the remarks set forth below, reconsideration of this application is respectfully requested.

REJECTION OF CLAIMS UNDER 35 U.S.C. §112, ¶2

Claims 41, 43 and 44-61 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the phrase: "wherein the G protein-coupled receptor .....increases an intracellular level of IP_3 when stimulated". The Examiner contends that the term "increases" is a relative term and, as such, one of skill in the art would not be reasonably apprised of the scope of the claim.

Without conceding to the correctness of this rejection, but instead as a way of further prosecution of the application, the Applicants have amended claim 44 to recite a G protein-coupled receptor (GPCR) that "is capable of stimulating intracellular IP_3 accumulation in a constitutive manner".

Withdrawal of this rejection is requested.

Claim 44 is further rejected under 35 U.S.C. §112, second paragraph, as being indefinite for not reciting precise hybridization or wash conditions.

Claim 44 as amended no longer recites hybridization or wash conditions.

As such, this rejection is moot and should be withdrawn.

REJECTION UNDER §101

Claims 29 and 41-61 stand rejected under 35 U.S.C. § 101 as lacking patentable utility. The Applicants respectfully traverse this rejection.

As an initial matter, it is the Applicants' understanding that this rejection is based on the Examiner's allegation that the asserted utility for the claimed receptor in motor control fails to meet the requirements of §101.

The Examiner contends that the claim-recited GPCR does not have a specific, substantial and credible utility (OA, p. 11.). Specifically, the Examiner contends that "the biological role of hRUP35 or its significance [are not disclosed]" and that further research is required to establish "a specific and substantial credible utility." (Id.) In maintaining this rejection, the Examiner outlines several distinct arguments over approximately 40 pages of text. Applicants believe that the Examiner's contention is based on the several distinct arguments which have been distilled from the Office Action and responded to below. Applicants hope that by distilling the Examiner's arguments in this fashion, the outstanding issues may be more effectively addressed. Applicants appreciate that the Examiner has worked diligently to detail the outstanding rejection and invite the Examiner to contact the undersigned directly if Applicants' distillation is deemed deficient.

Assertion of Utility Does Not Require Correlation to a Specific Disease

The instant specification unequivocally states that hRUP35 is involved in motor control.[1] At the filing date of the instant application, therefore, the utility for hRUP35 in motor control was known to the Applicants, and asserted in the instant application. After the filing date of the instant application, statements supporting hRUP35's role in motor control were independently

[1] See, e.g., page 19, lines 9-11 of the instant specification: "For example and not limitation, proteins located/expressed in areas of the thalamus [e.g., hRUP35] are associated with sensorimotor processing and arousal" and the last paragraph of the amendment to the instant specification, shown above: "RUP35 was specifically expressed in the thalamus of the brain, suggesting that RUP35 may play a role in sensorimotor processing and arousal". Text in brackets added by Applicants.

made by *Susens*.[2] Subsequently, hRUP35's role in motor control was independently confirmed by *Torres*[3] using knockout mice.

Notwithstanding the asserted utility in motor control, the Examiner states that "there is no disclosure of the specific association with a specific motor function, sensorimotor processing or arousal disorder" and that such determination would require further research (OA, p.11). The Examiner subsequently queries the Applicants to answer his question "what is the specific disorder or dysfunction that is specifically associated with claimed hRUP35[?]," and concludes that the asserted utility encompasses many different disorders. (OA, p.13). In order to provide context for the rejection with respect to specificity of motor function, the Examiner posits several lines of evidence that he contends are not disclosed by Applicants including: an identification of the presence of the receptor in diseased tissue; the presence of the receptor at elevated concentrations in diseased tissue; a correlation of the location and function of the receptor to create a treatment regimen; and a disease associated with the receptor. (OA, pp.14-15).

However, the Examiner does not cite any authority for the implicit contention that such details are required by the USPTO in order to establish a specific utility for a claimed invention. While disclosure of a specific disease correlation may be used by an Applicant to support an assertion of utility, the Examiner is going beyond the dictates of the USPTO Guidelines in requiring the Applicants to cite such disclosure in order to establish the utility of the claimed invention. In fact, the Examiner is not contending that the application lacks an asserted utility.

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[2] See, e.g., page 520, last sentence, of *Susens* (Neuropharmacology 2006 50:512-520), where *Susens* states "The presence of GPR139 [which is the same as hRUP35] in brain areas involved in motor control suggests a function as mediator in locomotor activity." This reference was cited by the Examiner in the Office Action mailed September 12, 2006, as reference U. In the Applicants' previous response, the *Susens* reference was inadvertently referred to as "Sensens" and, further, page 520 of *Susens* was inadvertently referred to as page 20. As such, we believe that this is responsive to the Examiner's statement on page 7, first paragraph, of the May 29, 2007, Office Action, that the *Susens* reference was not provided and therefore not considered. For the Examiner's convenience, a copy of the *Susens* reference is attached hereto. Text in brackets added by Applicants.

[3] See, e.g., *Torres et al.*, Abstract 328 of the 2006 Keystone Symposium. The Torres abstract reports that mutant mice lacking the mouse homolog of hRUP35 display a motor deficit. *Torres* was cited in a supplemental IDS in June 21 2006 as references AC. For the Examiner's convenience, a copy of the *Torres* reference is attached hereto.

Rather, he is just contending that the asserted utility is too broad and encompasses symptoms of different diseases and is not, therefore, specific enough to satisfy the requirements of §101. Again, Applicants cannot find any authority in the USPTO Guidelines for such a rejection. The Examiner argues that Example 12 of the Revised Interim Utility Guidelines ("RIUG") supports such a rejection. In fact, Example 12 supports Applicants' arguments that the asserted utility is sufficient. Example 12 suggests that utility may be derived from a disclosed "biological function or any disease or body condition that is associated with the isolated protein." (RIUG, Ex. 12, emphasis added. Accordingly, the Examiner's insistence that Applicants asserted utility is deficient absent disclosure of a specific disease correlation is not appropriate. As Example 12 makes clear, disclosure of a biological function or any disease or body condition is sufficient to establish utility. Applicants' asserted utility for the receptor in motor control represents both a biological function and a body condition. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection as based on this line of argument.

Assertion of Utility Does Not Require Identification of a Ligand

The Examiner additionally states that, with respect to the receptor, the determination of "said ligands and their specific use requires further research." (OA, p.12). However, the Examiner does not cite any authority for the implicit contention that identification of a ligand is required by the USPTO in order to establish a specific utility for a claimed invention. While disclosure of a ligand may be used by an applicant to support an assertion of utility, the Examiner is going beyond the dictates of the USPTO Guidelines in requiring the Applicants to cite such disclosure in order to establish the utility of the claimed invention. This is particularly true in the instant situation where the Applicants have shown that the receptor is active in the absence of ligand. Applicants respectfully request that the Examiner identify on what authority identification of a ligand is required by the USPTO in order to establish a specific utility for a claimed invention. Absent such authority, Applicants respectfully request that the Examiner reconsider and withdraw arguments based on identification of a ligand.

Applicant's Assertion of Utility is Not Based on Homology to Known GPCRs

The Examiner cites multiple references in support of his contention that "the utility of claimed receptor cannot be implicated solely from homology to known G-protein coupled receptors." (See, for example, OA, pp. 28-34). Oddly, Applicants do not believe that they have ever attempted to assert utility for hRUP35 based solely on homology to known GPCRs. If the Examiner disagrees, Applicants respectfully request that the Examiner identify where in the prosecution such assertions were made by Applicants. In the absence of such identification and in order to simplify ongoing prosecution, Applicants respectfully request that the Examiner withdraw these arguments as inapplicable.

Post-Filing Art is Not Relevant in Determining "Skill in the Art" at Time of Filing

The Examiner cites scientific literature to question such matters as the cells used in the instant application and the conclusions drawn therefrom. (i.e., OA, p.19). The Examiner concludes from this literature that a skilled artisan would believe further research was required in order to make Applicants' asserted utility credible. (Id.). However, in making these arguments, the Examiner cites many documents published after the filing date of Applicants' invention. Without addressing the merits of these arguments, Applicants believe that such hindsight analysis is completely inappropriate for a utility analysis and has no basis in the USPTO Guidelines. If the Examiner desires to discuss the "skilled artisan" or the thinking of one of skill in the art, such discussion should center on one of skill in the art at the time the application was filed. Applicants respectfully request that the Examiner identify on what authority post-filing documents may be utilized as a basis for establishing the skill of one of the art at the time of filing. Absent such authority, Applicants respectfully request that the Examiner reconsider and withdraw arguments based on post-filing art.

The Examiner's Utility Requirement is Inconsistent with the Law

i. Applicants have asserted a credible utility

An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101. MPEP § 2107.02 III A. The Court of Customs and Patent Appeals stated in *In re Langer*:

> As a matter of Patent Office Practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the entire claimed subject matter unless there is a reason for the skilled in the art to question the objective truth of the statement of utility or its scope." *In re Langer* 183 USPQ 288, 297 (CCPA 1974) (emphasis in original).

ii. The Examiner has not met the burden for a *prima facie* showing

To overcome the presumption of sufficient utility as asserted by the Applicant, the Examiner must carry the initial burden to make a *prima facie* showing of lack of utility and provide evidentiary basis for the conclusion. In other words, the Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objection truth of the statement of operability". *In re Gaubert*, 187 USPQ 664, 666 (CCPA, 1975).

In the present case, the Applicants have asserted in the instant specification that hRUP35 (which is encoded by the claimed polynucleotides) is involved in motor control, and thus has a substantial and real-world utility, for example, in identifying compounds that can be used to treat sensorimotor processing-related disorders. The Applicants have submitted *Susens* and *Torres*, which confirm that the asserted utility is credible.

In contrast, the Examiner has not provided any specific evidence or objective reason to question the objective truth of the Applicants' statements about the role of hRUP35 in motor control. In other words, in citing *Susens* and *Torres*, the Applicants have provided substantial evidence confirming hRUP35's asserted utility in motor control, and the Examiner has provided no specific evidence to contradict the Applicants' statements. Thus, the Applicants believe that the Examiner has not met the burden of making a *prima facie* showing of lack of utility. As such, this rejection should be withdrawn.

Since the Examiner has provided no evidence to support this rejection, the Examiner is requested, under MPEP § 2144.03[4], to provide an affidavit of personal knowledge as to why the person of ordinary skill would have reason to doubt the utility that is asserted in this case.

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[4] MPEP § 2144.03: "If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting

iii. Applicants' asserted utility is specific

According to the MPEP 2107.01, citing *In re Fisher*[5], it is important for Office personnel to distinguish between *general* and *specific* utilities. According to *In re Fischer*, general utilities are applicable to the broad class in which an invention belongs. For example, general utilities for a biopolymer include, for example, "as a probe to isolate other polynucleotides", "to make antibodies" or "as a marker to make a genetic map". The Applicants are not arguing that hRUP35 has a general utility. Rather, the Applicants argue that hRUP35 is specifically involved in motor control. *The asserted utility of hRUP35 is not applicable to all GPCRs*, and is therefore not a general utility.

The Applicants respectfully submit that the claimed polynucleotide should be treated no differently to other polynucleotides that can be used, for example, to identify drugs for the treatment of symptoms, e.g., inflammation and pain, that are associated with a number of diseases.

The Examiner's requirement that the Applicants point out specifically a particular disease to which hRUP35 is linked is a mis-interpretation of the law.

Summarizing the foregoing discussion, the Applicants believe the Examiner's rejection is based on a standard that is much higher than that required for satisfying 35 U.S.C. § 101. Thus, this rejection should be withdrawn.

Conclusion

The Applicants' prior arguments still stand and are incorporated herein but reiterated for the sake of brevity. In the event that the above arguments are found unpersuasive, the Applicants' prior arguments are hereby preserved for Appeal.

The Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2)".

[5] *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005)

REJECTIONS UNDER §112, ¶1 (ENABLEMENT - UTILITY)

Claims 29 and 41-46 are rejected as not meeting the "how to use" part of the enablement requirement of 35 U.S.C. § 112, first paragraph.

The basis for this rejection is the Examiner's contention that the claims are not supported by a patentable utility.

As such, it is believed that this rejection has been adequately addressed in the discussion in the preceding section of this response.

In view of the discussion in the preceding section of this response, this rejection should be withdrawn.

REJECTIONS UNDER §112, ¶1 (ENABLEMENT - SCOPE)

Claims 44-61 are rejected as not meeting the enablement requirements of 35 U.S.C. § 112, first paragraph. Specifically, the Examiner contends that: a) the claims lack a structure and functional limitation, b) the term "increases an intracellular level of IP_3" is meaningless, and c) the conditions for PCR are not recited in the claims. The Applicants respectfully traverse this rejection based on the amendments presented herein.

The Applicants have amended claim 44 herein (and, thus, claims 45-56) to recite that the "G protein-coupled receptor comprises an amino acid sequence having at least 90% identity to SEQ ID NO:16". In addition the claim has been amended to recite that the "G protein-coupled receptor is capable of stimulating intracellular IP_3 accumulation in a constitutive manner." The Applicants note that the claim has also been amended to remove the word "increasing" that had previously been objected to by the Examiner. Accordingly, the claim as amended recites clear structural and functional limitations. Further, the Applicants have amended claim 44 to remove reference to PCR, thus obviating the third part of the Examiner's rejection. The Applicants therefore respectfully requested that the Examiner reconsider and withdraw the outstanding rejection.

REJECTIONS UNDER §112, ¶1 (WRITTEN DESCRIPTION)

Claims 44-61 are rejected as not meeting the written description requirements of 35 U.S.C. § 112, first paragraph. Specifically, the Examiner contends that: a) the claims lack a structure and functional limitation, b) the term "increases an intracellular level of IP_3" is meaningless, and c) the conditions for PCR are not recited in the claims. The Applicants respectfully traverse this rejection based on the amendments presented herein.

The Applicants have amended claim 44 herein (and, thus, claims 45-56) to recite that the "G protein-coupled receptor comprises an amino acid sequence having at least 90% identity to SEQ ID NO:16". In addition the claim has been amended to recite that the "G protein-coupled receptor is capable of stimulating intracellular IP_3 accumulation in a constitutive manner." The Applicants note that the claim has also been amended to remove the word "increasing" that had previously been objected to by the Examiner. Accordingly, the claim as amended recites clear structural and functional limitations. Further, the Applicants have amended claim 44 to remove reference to PCR, thus obviating the third part of the Examiner's rejection. The Applicants therefore respectfully requested that the Examiner reconsider and withdraw the outstanding rejection.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AREN-021CIP.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date: October 30, 2007

By: /James S. Keddie, Reg. No. 48,920/
James S. Keddie, Ph.D.
Registration No. 48,920

Enclosures: RCE and copies of *Susens* and *Torres* references.

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231

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